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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,705	04/12/2007	Jurgen Dannenmaier	PN0423-US01	5049

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EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
04/11/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,705	DANNENMAIER ET AL.	
	Examiner	Art Unit	
	Philip R. Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

In the reply filed 2/1/11, applicant amended claims 29, 40, and 57-65. Claims 29-65 are currently pending.

Response to Arguments

Applicant's arguments have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly considered prior art. Specifically, Verkaart reasonably suggests the placement of a flexible hydrophobic filter membrane within a lid at the top portion of a degassing device.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 29, 30, 41-45, 48-50, 55, 58-62, and 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay et al. (US 4,433,971) in view of Verkaart et al. (US 5,707,431).

2. With respect to Claim 29, Lindsay et al (hereafter 'Lindsay') teaches a fluid distribution module comprising a degassing device 11, said degassing device

comprising a first chamber 58 having an inlet for a liquid and a second chamber 184 having an outlet 62 for discharging the liquid and a dome shaped lid 186 at the top portion thereof that closes the opening at the top of the second chamber. The lid comprises a vent 188 that allows for the removal of gas from the second chamber. Further, the vent is in communication with a hydrophobic membrane 194 that closes the flow path extending from the vent to the outlet. The first chamber partially extends within the second chamber and communicates therewith through an upper passageway (203, 204); the second chamber having an upstream portion that extends above said passageway and a downstream portion extending below the passageway (see Figure 2). Lindsay further teaches a connecting structure having a first conduit 58 and a second conduit 64 disposed therein. The first conduit 58 comprises a first end capable of connection to a discharge tube from an oxygenator (from discharge tube 22) and a second end connected to the inlet of the first chamber. The second conduit 64 comprises a first end capable of connection to the outlet 64 of the second chamber and a second end for connection to a blood return tube (66, 76) to a patient.

Lindsay teaches the device substantially as claimed, but does not specifically teach that the hydrophobic membrane is disposed within the lid portion, such that it closes the opening at the upper portion of the second chamber.

Verkaart teaches a gas elimination system for use with extracorporeal treatment comprising a degassing device that has a first chamber connected to a second chamber, wherein air is separated from the blood and removed through a vent 6 at the top portion of the system. Specifically, Verkaart teaches that the top portion of the

system comprises a lid portion 18 comprising a vent 6 and a flexible hydrophobic membrane 16 that is disposed within the lid portion, such that it closes the upper opening of the second chamber. Like Lindsay's air removal system, this configuration substantially allows gas to pass to the air outlet without allowing blood to do so. Additionally, the placement of the hydrophobic filter within the second chamber allows a filter having a larger cross-sectional area to be used, thereby allowing gasses to be removed from the system at higher flow rates (Column 2, Lines 10-13). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the degassing device of Lindsay with a hydrophobic membrane disposed within the lid portion of the blood-gas separation chamber, as suggested by Verkaart, in order to provide a well known means for increasing the flow capacity of the system.

3. With respect to Claim 30, Lindsay teaches a third conduit 36 capable of connection between a post-dilution infusion tube and to the second end of the first conduit 56.

4. With respect to Claims 45 and 60, the upper rim 204 of the passageway between the first and second chambers is substantially angled (Column 5, Lines 7-13), such that the downstream part of the second chamber asymmetrically surrounds the upper part of the first chamber.

5. With respect to Claims 48 and 61, Lindsay teaches that the passageway (203, 204) from the first chamber to the second chamber of the degassing device comprises a cross section that is smaller than the cross section of the second chamber.

6. With respect to Claims 49 and 62, the second chamber is disposed around the first chamber. Further, the passageway comprises an angled rim 204, such that blood spills over to the side opposite from the outlet 62, then flows around the cylindrical passageway to the outlet (column 5, lines 7-13). Therefore, blood will flow through the second chamber in a circular manner (i.e. tangential to the hydrophobic filter).

7. With respect to Claims 50, 53, and 64, the second chamber is disposed circumferentially around the first chamber, such that the degassing device and associated flow path are substantially umbrella-shaped. Fluid that overflows from the first chamber will flow into the second chamber.

8. With respect to Claim 52, the first chamber has a downstream portion having a cross-sectional that is substantially the same as at least a portion of the cross-section of the passageway (203, 206) between the first and second chambers.

9. With respect to Claims 54 and 65, Lindsay teaches that the second chamber comprises a dome-shaped top, such that the chamber has a large cross-sectional diameter adjacent the passageway (206, 203) and a narrow cross-sectional diameter at the top portion thereof. The second chamber extends upward through opening 188, such that the cross sectional diameter adjacent the filter is substantially smaller than that of the passageway.

10. With respect to Claim 55, the outlet 62 of the second chamber is disposed at the lowest point thereof.

11. With respect to Claims 41-44 and 58-59, Lindsay and Verkaart reasonably suggest the device substantially as claimed, but do not specifically teach the claimed

cross-sectional diameter ratios between the first and second chambers of the degassing device (and the resulting flow rates). However, it has been held that the mere optimization of a prior art device through routine experimentation does not constitute a patentable improvement in the art (see MPEP § 2144.05). In this case, Lindsay clearly suggests a variety of diameter ratios to provide optimal fluid flow rate from the first chamber to the second chamber Column 4, Line 61 through Column 5, Line 34). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the diameter ratio of the first and second chambers of the degasser device in order to provide an optimal flow velocity in the second chamber, thereby maximizing the speed and effectiveness of air removal.

12. Claims 31-33 and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay in view of Verkaart, and further in view of Buckberg (US 5,011,469). Lindsay and Verkaart reasonably suggest the device substantially as claimed, and Lindsay further teaches that the system comprises a withdrawal line 20 connecting the patient access point to the pump 28 and an infusion line 30 for infusing a medicament into the blood. Lindsay, however, is silent regarding whether the withdrawal line comprises pumps on *both sides* of the oxygenator (such that the withdrawal conduit comprises a fourth conduit extending from the patient access to a pump, and a fifth conduit that extends from said pump to said oxygenator.

However, it is commonplace in the art of extracorporeal treatment that a plurality of pumps may be used to drive fluid through the system. Buckberg (hereafter Buckberg

'469) teaches an extracorporeal cardioplegia delivery system for oxygenating blood comprising a withdrawal conduit (29, 40), a withdrawal pump 18, an oxygenator 20, a cardioplegia pump 24, and an infusion lumen. The withdrawal pump 18 is configured to apply a negative pressure to the withdrawal conduit, such that blood is sucked through the conduit. Once blood reaches the pump 18, it applies positive pressure to move the blood forward through the oxygenator. Once the blood passes the oxygenator and mixes with other fluids, the cardioplegia pump 24 will reinfuse the fluid into the body. Specifically, Buckberg '469 teaches that the use of a withdrawal pump 18 is commonplace because it allows for separate flow rates on either sides of the oxygenator. This is crucial to the functionality of a cardioplegia delivery device because other fluids are being added to the blood (as is the case in both Buckberg '569 and Lindsay). See Column 6, Lines 10-30 and Column 10, Line 66 through Column 11, Line 19). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to place a withdraw pump upstream of Lindsay's oxygenator (such that the withdrawal line comprises the fourth conduit and fifth conduit as discussed above), in order to provide a means for withdrawing blood from the patient at a rate independent of the patient's physiological blood pressure.

13. Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay in view of Verkaart, and further in view of Strauss et al. (US 5,837,905). Lindsay and Verkaart reasonably suggest the device substantially as claimed, but do not specifically teach that the system is connected by means of a periphery with a

plurality of sockets attached thereto. Strauss et al (hereafter 'Strauss') teaches a unitary cardioplegia flow control and monitoring cassette comprising a plurality of predefined flow paths having a plurality of sockets onto which tubing segments are mounted. This system allows a plurality of disposable flow conduits to be attached to reusable elements of a blood treatment system, such as blood pumps and sensors (see Abstract and entire disclosure). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the extracorporeal treatment device of Lindsay and Verkaart with Strauss' unitary cassette having a plurality of sockets for the connection of fluid tubing in order to provide a well known means for organizing blood tubing and reusing expensive elements of a blood treatment system.

14. With specific regard to the claimed laterally-extending loop, it has been held that the mere rearrangement of parts does not constitute a patentable improvement in the art when said rearrangement does not result in a non-obvious improvement (see MPEP § 2144.04). In this case, Lindsay teaches the claimed device except for the use of a periphery with a plurality of sockets attached thereto, and Strauss reasonably suggests that a cardioplegia system may be mounted on a cassette with tubes mounted at the appropriate positions. It would have been obvious to rearrange the specific orientation of the tubing such that a lateral loop is formed to connect respective inlets and outlets, because doing so would not substantially change the operation of the device.

15. Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay in view of Verkaart, and further in view of Bringham et al. (US 4,698,207).

Lindsay and Verkaart reasonably suggest the device substantially as claimed, and Lindsay further teaches that the second portion of the degassing device comprises an outer cylindrical wall surrounding the first chamber. Lindsay, however, does not specifically teach that the outer cylindrical wall is beveled. Bringham et al. (hereafter 'Bringham') teaches an integrated oxygenator and gas removal device wherein blood is inserted tangentially around the inlet to the oxygenator. Bringham specifically teaches that tangential flow is commonly used because it quickly dislodges air bobbles from blood due to buoyancy and centrifugal forces (Column 8, Lines 3-9). Further, Bringham teaches that the walls of the tangential flow path are beveled, such that a narrow annular opening is formed; thereby further promoting the separation of gas and blood (Column 5, Lines 1-13). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the cylindrical outer flow path of Lindsay with Bringham's beveled, tangential path in order to provide for more efficient separation of air bubbles from blood.

16. Claims 51 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay in view Verkaart, and further in view of Buckberg (US 5,643,191). Lindsay and Verkaart reasonably suggest the device substantially as claimed, but do not specifically teach that the hydrophobic membrane is disposed adjacent the accumulation of gas bubbles. Buckberg (hereafter Buckberg '191) teaches a cardioplegia treatment system comprising a degassing chamber for removing gas from blood. Blood passes into a first chamber, then rises into a second chamber. Once in

the second chamber, gas bubbles rise to the top portion thereof, where they contact a hydrophobic membrane 68. Further, the second chamber comprises a bubble screen that forces gas bubbles to the top of the chamber. The hydrophobic membrane has a porosity such that air is allowed to pass therethrough, but liquids are substantially prevented from passing. Further, a one-way pressure-activated valve is disposed distally of the membrane, such that non-sterile outside air does not come into contact with the blood. This arrangement will result in a constant stream of gas bubbles moving toward the top of the second chamber. It is the examiner's position that this configuration provides substantially the same functionality as the claimed device. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the degassing device of Lindsay and Verkaart with the hydrophobic membrane and bubble screen of Buckberg in order to provide an alternate means for removing gas from blood, thereby preventing gas bubbles from being infused into the body.

17. Claims 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindsay in view of Verkaart and Buckberg '569, and further in view of Strauss. Lindsay, Verkaart, and Buckberg '569 reasonably suggest the device substantially as claimed, but do not specifically teach that the system comprises a plurality of pressure measuring chambers corresponding to each of the flow paths. Strauss teaches a unitary cardioplegia flow control and monitoring cassette comprising a plurality of predefined flow paths having pressure-sensing cells (38, 40, 46, 48) attached thereto. The pressure-sensing cells comprise a first compartment that allows fluid to flow through the

conduits, and a second compartment that is configured to determine the pressure of the fluid in said conduits. The first and second compartments of the pressure sensors are separated by membrane diaphragms (Column 7, Lines 40-61). Strauss teaches that it is commonplace in the art to dispose pressure sensors along flow paths in a medical fluid cassette because doing so allows the speed of the pumps to be adjusted by the controller in real time to vary the ratio of blood and crystalloid (see Abstract and entire disclosure). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the blood treatment device of Lindsay, Verkaart, and Buckberg '569 with Strauss' membrane-type pressure sensors in order to provide a well-known means for monitoring and controlling fluid flow at based on pressures at different points in the fluid circuit.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R. Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Philip R Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
8 April 2011